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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER	
SAJJADI, FEREYDOUN GHOTB	
ART UNIT	**PAPER NUMBER**
1633	

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/800,333	HEKIMI ET AL.	
	Examiner	Art Unit	
	Fereydoun G. Sajjadi	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-31 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-31 are pending in this application.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 6-8 and 29-31, drawn to a method of identifying a compound that modulates the level of a lipid or lipoprotein and a method for selecting nematodes, comprising contacting said compound with test nematodes and comparing a phenotype resulting from said compound's contact with said nematode, classifiable in class 424, subclass 9.1.

II. Claims 2 and 29-31, drawn to a method for isolating a gene that modulates the level of a lipid or lipoprotein comprising subjecting nematodes that comprise at least one mutation in the clk-1 gene to mutagenesis, classifiable in class 435 subclass 455.

III. Claims 3-5 and 29-31, drawn to a method for identifying a gene that modulates the level of a lipid or lipoprotein comprising contacting test nematodes that comprise at least one mutation in the clk-1 gene with a nucleic acid that reduces the level of expression of a nematode gene, classifiable in class 536 subclass 24.5.

IV. Claims 9-13 and 19-20, drawn to an isolated nucleic acid comprising dsc-4 gene or dsc-3 gene, , and an expression vector and cell comprising said isolated nucleic acids, classifiable in class 435, subclass 320.1.

V. Claims 14-17, drawn to an isolated polypeptide, fragment or variant polypeptide, comprising DSC-4 or DSC-3, classifiable in class 530, subclass 350.

VI. Claim 18, drawn to an antibody that binds to a polypeptide comprising DSC-4 or DSC-3, classifiable in class 530, subclass 387.1.

VII. Claims 21-22, drawn to a transgenic non-human animal comprising a transgene that comprises dsc-4 or dsc-3 genes, classifiable in class 800, subclass 9.

VIII. Claim 23 and 27, drawn to a method of making and isolating a MOLL polypeptide, classifiable in class 530, subclass 350.

IX. Claim 24 and 28, drawn to a method for identifying a compound that binds a MOLL polypeptide comprising detecting the binding of said MOLL polypeptide to said test compound, classifiable in class 514, subclass 2.

X. Claims 25-26 and 28, drawn to a method for preventing or treating atherosclerosis or a dyslipidemia disorder in humans, comprising administering an agonist or an antagonist of a MOLL polypeptide, classifiable in class 514, subclass 2.

2. Should applicant elect any of Groups I-X, applicant is required to choose **one** specific dsc gene identified by SEQ ID NO: 1 or SEQ ID NO: 7 and one specific DSC polypeptide identified by SEQ ID NO: 2 and SEQ ID NO: 8. Each of the nucleic acids set forth in SEQ ID NOS: 1 and 7 and their corresponding polypeptides set forth in SEQ ID NOS: 2 and 8, is structurally and likely functionally distinct and each is capable of separate utility. Therefore, the genes and their corresponding peptides do not constitute a proper Markush group. The search and examination of said distinct DSC genes and dsc polypeptides is not coextensive and would constitute undue burden. **This is not an election of species requirement.**

The inventions are distinct, each from the other because of the following reasons:

Restriction is deemed to be proper because these methods constitute patentably distinct inventions they are not disclosed as capable of use together or they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

Inventions I-III and VIII-X are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the methods of Groups I and II are distinct, each from the other because invention I is directed to a method of identifying a compound that modulates the level of a lipid or lipoprotein and a method for selecting nematodes, whereas the method of Group II is directed to a method for isolating a gene that modulates the level of a lipid or lipoprotein comprising subjecting nematodes that comprise at least one mutation in the clk-1 gene to mutagenesis. The gene isolation and mutagenesis of invention II are not required for the method of invention I. Each method is directed to a distinct goal or a materially distinct step, is capable of separate use and employs particulars not commonly shared. Hence, the search and

examination of their respective subject matter encompasses non-coextensive subject matter, imposing an undue burden for combined examination.

Invention III is directed to identifying a gene comprising contacting test nematodes that comprise at least one mutation in the clk-1 gene with a nucleic acid that reduces the level of expression of a nematode gene. Invention III is distinct from the methods of Groups I and II because it does not require the mutagenesis step of Group II, and the nucleic acid of Group III, that may be antisense molecule is not required for the method of Group I. Hence each method is directed to a distinct goal or a materially distinct step, is capable of separate use and employs particulars not commonly shared. Hence, the search and examination of their respective subject matter encompasses non-coextensive subject matter, imposing an undue burden for combined examination.

Invention VIII is distinct from the methods of Groups I-III and IX-X. Invention VIII is directed to a method of making and isolating a MOLL polypeptide, said method not required for the compound identification or gene isolation methods of Groups I-III and IX. The method of Group III is further not required for the treatment method of Group X. Hence each method is directed to a distinct goal or a materially distinct step, is capable of separate use and employs particulars not commonly shared. Hence, the search and examination of their respective subject matter encompasses non-coextensive subject matter, imposing an undue burden for combined examination.

Invention IX is directed to a method for identifying a compound that binds a MOLL polypeptide. The method of Group IX may be carried out *in vitro*. As such, it is distinct from the compound identification method of Group I and not required for any of the methods in Groups II-III or IX-X. Hence each method is directed to a distinct goal or a materially distinct step, is capable of separate use and employs particulars not commonly shared. Hence, the search and examination of their respective subject matter encompasses non-coextensive subject matter, imposing an undue burden for combined examination.

Invention X is directed to a method for preventing or treating atherosclerosis or a dyslipidemia disorder in humans. As said treatment is not required for the nucleic acid isolation or compound identification methods of Groups I-III or VIII-IX, the invention is distinct. Each method is directed to a distinct goal or a materially distinct step, is capable of separate use and

employs particulars not commonly shared. Hence, the search and examination of their respective subject matter encompasses non-coextensive subject matter, imposing an undue burden for combined examination.

Inventions IV, V and I, , IX, X are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the compound identification method of Groups I and IX or treatment method of Group X will not result in the identification of the nucleic acids of Group IV or the polypeptides of Group V. Hence, the search and examination of their respective subject matter encompasses non-coextensive subject matter, imposing an undue burden for combined examination.

Inventions II-III and IV-V are directed to related processes and products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are distinct, because the method of Groups II and III may result in the identification of genes and polypeptides other than dsc-3 or dsc-4.
Hence, the search and examination of their respective subject matter encompasses non-coextensive subject matter, imposing an undue burden for combined examination.

Inventions IV-V and VI-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are nucleic acids, polypeptides and antibodies and transgenic animals. Hence, the search and examination of their respective subject matter encompasses non-coextensive subject matter, imposing an undue burden for combined examination.

Inventions VIII and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process of making a MOLL polypeptide may be practiced with a nucleic acid

that is distinct from dsc-3 or dsc-4. Hence, the search and examination of their respective subject matter encompasses non-coextensive subject matter, imposing an undue burden for combined examination.

Inventions VI and I-III, VII-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are an antibody (Group VI), and methods of isolating a gene (Groups II and III), methods of identifying compounds (Groups I, and IX), transgenic animals (Group VII), a method of making a polypeptide (Group VIII), and a method of treating or preventing atherosclerosis (Group X), that do not require the antibody of Group VI. Hence, the search and examination of their respective subject matter encompasses non-coextensive subject matter, imposing an undue burden for combined examination.

Inventions VII and I-V, X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are a isolated nucleic acid (Group IV), isolated polypeptide (Group V), transgenic non-human animal (Group VII), and methods of isolating a gene (Groups II and III), methods of identifying compounds (Groups I, and IX), a method of making a polypeptide (Group VIII), a method of treating or preventing atherosclerosis (Group X), that do not require the transgenic animal of Group VI. Hence, the search and examination of their respective subject matter encompasses non-coextensive subject matter, imposing an undue burden for combined examination.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper

restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their recognized divergent subject matter, different classification, and different search requirements, restriction for examination purposes as indicated is proper. The combined search and examination of the different products and methods of the inventions in Groups I-IX, would not be coextensive and would impose a serious burden on the examiner (see MPEP § 808.02).

3. This application contains claims directed to the following groups of patentably distinct species of the claimed invention:
For Groups I-III – Applicant is required to choose a specific phenotype, as recited in claims 1-3, 6, 8 and 31. The nematode associated phenotypes relating to the length of defection cycle, the rate of germline vs. soma development, the rate of embryonic and post-embryonic development, expression profile of one or more genes, and the distribution of a lipid or lipoprotein are each distinct parameters, requiring non-coextensive search and examination of their respective subject matter, imposing an undue burden on the examiner.

For Groups III – Applicant is required to choose a specific nucleic acid, as recited in claim 4. The antisense nucleic acid and double-stranded RNA molecule, are each structurally and functionally distinct and further capable of separate utility, because an antisense nucleic acid may comprise a single stranded deoxyribonucleotide. The search and examination of their respective subject matter is non-coextensive and imposes an undue burden on the examiner.

For Groups X – Applicant is required to choose a specific pharmaceutical composition, as recited in claim 25. An agonist and an antagonist of a Moll polypeptide, are each structurally and functionally distinct and further capable of separate utility. The search and examination of their respective subject matter is non-coextensive and imposes an undue burden on the examiner.

Applicant is required under 35 U.S.C. §121 to elect a single disclosed species for each of the groups above, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims, 1-8, 25 and, 31 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, and/or because of the patentably distinct species are listed above, it would be unduly burdensome for the examiner to search and examine all of the subject matter being sought in the presently pending claims, and thus, restriction for examination purposes as indicated is proper.

Applicant is advised that the response for this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst William Phillips, whose telephone number is **(571) 272-0548.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fereydoun G. Sajjadi whose telephone number is **(571) 272-3311**. The examiner can normally be reached Monday through Friday, between 7:00 am-4:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on **(571) 272-0731**. The fax phone number for the organization where this application or proceeding is assigned is **(571) 273-8300**. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

For all other customer support, please call the USPTO Call Center (UCC) at **(800) 786-9199.**

Fereydoun G. Sajjadi, Ph.D.
Examiner, USPTO, AU 1633

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER